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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,120	09/25/2001	Marvin L. Schilling	BWS-00-07	9970

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BERND W. SANDT
900 Deerfield Court
Midland, MI 48640

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/31/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/964,120

Applicant(s)

SCHILLING ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt of Amendment E received on August 14, 2003 is acknowledged. Claims 18-32 is pending in this application. Claims 1-17 have been cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-19, 21-22, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 59-088065 in view of Ueno et al (4789497).

JP teaches preparation of edible bone and marrow. The method includes soaking, disinfecting, and washing the edible parts in sodium hypochlorite for one hour. The parts are ground and mixed with soy lecithin at a temperature that does not degrade the protein. See page 2 of translated document. The powder is then hot air dried.

JP does not teach the use of NaCl or KCl in the solution.

Ueno et al teach the process of dehydration of fish meat. Ueno teaches dehydration removes extra water and the well-known method of dehydration using sodium chloride, magnesium chloride, or calcium chloride at the time of washing. This addition promotes the bonding of proteins with Na, Mg, or Ca ions resulting in reduction in the charge of proteins and eases dehydration. Ueno et al teaches the object of washing is to remove factors that cause denaturation of proteins (col. 1, line 16 and lines 44-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use NaCl or KCl in JP's washing method before dehydrating the product method of dehydration since Ueno teaches the state of the art in regards to dehydration. One would be motivated to add the salts to facilitate dehydration and prevent denaturation of the protein. Further one would be motivated to combine both the salts and antimicrobials in the washing method prior to drying the product since both methods are geared towards preserving the proteins in the product.

Response to Arguments

Applicant argues that JP is based on a solution of lecithin and a solution of hypochlorite, then ground into ground particles, washed again, and dehydrated to the proper content. It is argued that the reference does not teach what this proper water content is. It is argued that there is no teaching that the pulverization is done at temperatures that prevents denaturization. Applicant argues that although sodium hypochlorite is taught, there is not teaches that this is used in the dehydration step.

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Applicant argues that Ueno only teaches mechanical dehydration and there is not suggestion of thermal dehydration. Applicant further argues the motivation to combine.

Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., water content) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner points out that claim 18 recites "until the water content is reduced" without a numerical or quantifiable value. As recognized by the applicant, JP clearly teaches "dehydrating to proper water content"; therefore it is clear that JP reduces the water content. The definition of dehydration is reducing the water content in a given material.

Secondly, the examiner point out that the claims are directed toward a method of dehydration of water containing proteinaceous substances. The first instant process step is combining with an antimicrobial agent and salt. This is clearly taught by JP wherein the marrow or bone of an animal (the water containing "proteinaceous substance") is washed and disinfected by combining it with sodium hypochlorite (the antimicrobial). Therefore this step is satisfied by the prior art. The second instant step is heating the mixture in particulate form at a temperature that preserves protein activity and reducing the water content. JP teaches grinding the bone or marrow, which forms the particulate form. The JP teaches mixing the particulate form with a selective additive (soy lecithin) at a temperature below denaturization. Note that heating the mixture

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inherently reduces water content. Therefore, JP satisfies this instant step. Further, the examiner points out that the claim language does not exclude additional process steps. Thus, even though JP teaches that the powder again can be washed and heated again and eventually may be air-dried or freeze dried, the claim language does not exclude these steps. Further, these additional process steps still yield the same dehydrated product.

In regards to applicant's arguments that it is not clear that throughout the process that JP uses steps that prevent denaturization, it is clear from JP statement "under temperatures not allowing for degeneration" that the prevention of denaturation is critical. Further on page 3, JP states that manufactured powder contains protein and is rich in nutrients; therefore it is clear that the preserving the protein is critical for JP.

In regards to the argument that JP teaches a solution of lecithin, the examiner points out that the applicant's claim language does not exclude other ingredients in the "mixture". Further the applicant does not limit the "mixture" to a solid form therefore the mixture can be in solution form. In regards to the dependent claim of adding salt in powder form, the examiner points out that salt naturally occurs in nature as a salt. Therefore, even if salt is added to a solution, it satisfies the claim limitation since the claim merely recites wherein the salt is used in a powder form. Obviously since salt occurs naturally in a solid form, it is used in a solid form.

The only teaching that is lacking is that JP does not teach salt in the process. Therefore the examiner solely relies on Ueno to teach the salt. As the applicant is aware that the primary reference does not have to teach all the limitation of the invention;

otherwise it would be said to anticipate the instant invention. The primary reference merely has to suggest the broad nature of the invention. The secondary reference teaches background of dehydration and the conventional use of salt in the process of dehydration. Further, Ueno teaches the salt is added at the time of washing to remove factors that cause denaturization. Therefore, one would be further motivated to add salt in JP's washing step to additionally prevent protein denaturization. The fact that Ueno teaches mechanical dehydration is irrelevant since JP covers the broad aspect of the invention.

Claims 20, 23-26, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 59-088065 in view of Ueno et al (4789497) in further view of Puppolo (5,562,535).

JP teaches preparation of edible bone and marrow. The method includes soaking, disinfecting, and washing the edible parts in sodium hypochlorite for one hour. The parts are ground and mixed with soy lecithin at a temperature of less 15 Celsius (59 Fahrenheit) that does not degrade the protein. See page 2 of translated document. The powder is then hot air dried. Ueno teaches the conventional use of salt during dehydration.

The references do not specify the water content of the resultant product. The hot-air temperature is not specified.

Puppola teaches a method of producing dehydrated shark cartilage without denaturing the proteins. The reference teaches that prior art methods of dehydrating such as convection ovens, vacuum ovens, and freeze drying techniques use

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temperatures that are high enough to cause the loss of proteins (column 1, lines 5-16).

After the undesirable components are removed from the cartilage, the removal of all water and solvent is accomplished by drying the product in a sonic chamber at 85 degrees Fahrenheit or lower (col. 2, lines 34-45). This temperature does not denature the proteins and removes all the solvent and water. See column 2, lines 34-35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of JP and Puppolo and utilize the instant temperature in JP's "hot air dried step". One would be motivated to look to Puppolo and since Puppolo teaches that in order to prevent denaturation of proteins and remove all water content, a temperature of 85 Fahrenheit should be utilized. Therefore, one would be motivated to look to Puppolo to prevent denaturization and remove all water from a JP's material.

Claim 18-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (5,645,851) in view of Ueno et al (4789497) in further view of Puppolo (5,562,535).

Moore teaches the obtaining Type II collagen from chicken cartilage (abstract). The chicken is soaked in a solution containing sodium chlorite and chlorine to remove surface contamination. The cartilage is removed from the chicken flesh and soaked in hydrogen peroxide to sterilize the cartilage without denaturing the protein. (Note example 1). The product of example 1 can be dried at an average temperature of 110 Fahrenheit to remove the water content (example 12).

Moore does not teach adding salt with the hydrogen peroxide during the sterilization step.

Ueno et al teach the process of dehydration of fish meat. Ueno teaches dehydration removes extra water and the well-known method of dehydration using sodium chloride, magnesium chloride, or calcium chloride at the time of washing. This addition promotes the bonding of proteins with Na, Mg, or Ca ions resulting in reduction in the charge of proteins and eases dehydration. Ueno et al teaches the object of washing is to remove factors that cause denaturation of proteins (col. 1, line 16 and lines 44-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use NaCl or KCl in Moore's sterilization step before heat dehydration. One would be motivated to add the salts to facilitate dehydration and prevent denaturation of the protein during dehydration. Further one would be motivated to combine both the salts and antimicrobials in the washing method prior to drying the product since both references methods are directed towards preserving the proteins in the end-product.

Although the water-content is not specified, it is deemed an obvious skill in the art to prolong the heating step till the desired water content is yielded. One would be motivated to do so since Moore teaches that reducing the water content prolong the shelf-life of the product (example 12).

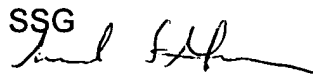
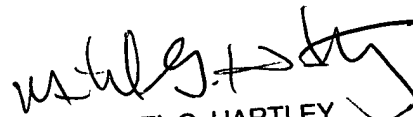
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG


10/22/03
MICHAEL G. HARTLEY
PRIMARY EXAMINER